



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,225	11/14/2003	Michael W. Mullaney	42620.17	2542

7590 01/10/2011
Dustin T. Johnson
Haynes and Boone, LLP
Suite 700
2323 Victory Avenue
Dallas, TX 75219

EXAMINER

SEVILLA, CHRISTIAN ANTHONY

ART UNIT	PAPER NUMBER
----------	--------------

3775

MAIL DATE	DELIVERY MODE
-----------	---------------

01/10/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/714,225	Applicant(s) MULLANEY, MICHAEL W.	
	Examiner CHRISTIAN SEVILLA	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-16 and 20-29 is/are pending in the application.
- 4a) Of the above claim(s) 20-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-16 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/12/2010, 12/14/2010</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed November 8, 2010 is acknowledged. Amended claim 13 has been entered. New claims 20-29 have been entered. Claims 8-16 and 20-29 are pending.

Election/Restrictions

Newly submitted claims 20-28 are directed to an invention that is distinct from the invention originally claimed because the inventions as claimed can have a materially different design, mode of operation, function, or effect. See MPEP 802.01. The originally claimed invention can be operated without the use of a computer. The newly presented claims can be operated with the use of a computer.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-28 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

Applicant's arguments filed November 8, 2010 have been fully considered but they are not persuasive.

Applicant argues the Ettinger reference fails to disclose how positions might be determined {p. 12, lines 3-19}. The Examiner respectfully disagrees. In response, positions of arms 29 are determined manually by the surgeon during normal use of the device {p. 2, right col., lines 16-67}. Further, various parameters describe motion of the arms 29. The values of the parameters satisfy simultaneous equations (e.g., Newton's laws). The specific paths taken by arms 29 during alignment of bone fragments A and B are solutions to additional equations of motion that are determined manually by the surgeon in order to bring bone fragments A and B into alignment.

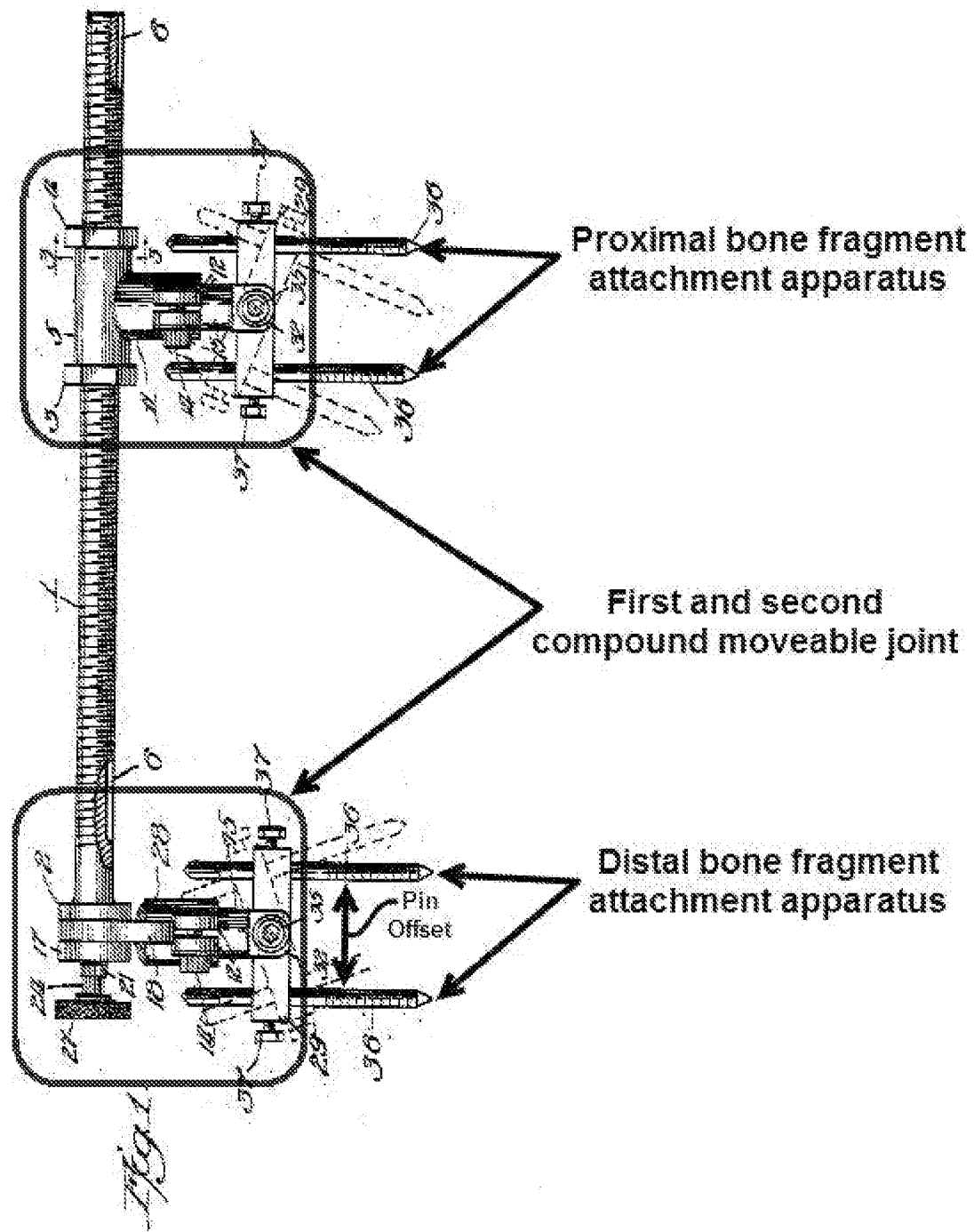
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-12 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ettinger (US 2250417).



Regarding claim 8, Ettinger discloses a) characterizing a mounting condition for a proximal bone fragment attachment apparatus (36) and a distal bone fragment attachment apparatus (36), as shown in annotated Fig. 1 above; b) determining a first

Art Unit: 3775

set of fixator characteristics, wherein the first set of characteristics correspond to physical dimensions of the fixator and initial fixator settings {*e.g.*, configuration of device before adjusting screw supporting arms 29; p. 2, right column, lines 35-40}; c) determining a deformity correction matrix by solving a plurality of simultaneous equations, wherein the equations correspond to kinematic equations; d) solving for a second set of fixator settings by equating the deformity correction matrix to a deformity correction transform; and e) reconfiguring the deformity correcting fixator based on the second set of fixator settings {*e.g.*, configuration of device after adjusting screw supporting arms 29; p. 2, right column, lines 35-40}.

Regarding claim 9, Ettinger discloses the deformity-correcting fixator comprises a unilateral fixator including a first and a second compound movable joint, as shown in annotated Fig. 1 above, wherein each compound movable joint provides deformity correction in two degrees of freedom, and a strut assembly, and a strut assembly which provides a third degree of freedom for each compound movable joint.

Regarding claim 10, Ettinger discloses setting the first compound movable joint and the second compound movable joint according to the solution for the second set of fixator settings; and repeating steps a) through d) as necessary {*i.e.*, no repeating steps are necessary} to adjust the first compound movable joint and the second compound movable joint over time.

Regarding claim 11, Ettinger discloses the step of characterizing a mounting condition for a proximal bone fragment attachment apparatus and a distal bone fragment attachment apparatus further comprises the steps of: a) determining an axial

Art Unit: 3775

rotation {via screw 35} for a proximal bone fragment attachment apparatus; b) determining an anterior-posterior rotation {e.g., relative position of plate 17 and segmental member 18} for the proximal bone fragment attachment apparatus; c) determining a lateral rotation for the proximal bone fragment attachment apparatus; d) determining a pin offset for the proximal bone fragment attachment apparatus; repeating steps a) through d) for a distal bone fragment attachment apparatus; and determining the bone length.

Regarding claim 12, Ettinger discloses parameters for offsets and joint rotations {zero values if they do not exist} of joints and clamps {e.g., the first and second compound moveable joints in annotated Fig. 1 above}.

Regarding claim 29, Ettinger discloses a) characterizing a mounting condition for a proximal bone fragment attachment apparatus (36) and a distal bone fragment attachment apparatus (36), *as shown in annotated Fig. 1 above*; b) determining a first set of fixator characteristics, wherein the first set of characteristics correspond to physical dimensions of the fixator c) determining a deformity correction matrix by solving a plurality of simultaneous equations, wherein the equations correspond to kinematic equations; d) solving for a second set of fixator settings by equating the deformity correction matrix to a deformity correction transform; and e) reconfiguring the deformity correcting fixator based on the second set of fixator settings {e.g., configuration of device after adjusting screw supporting arms 29; p. 2, right column, lines 35-40}.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ettinger in view of Meulenbrugge, *et al.* (US 5713357; "Meulenbrugge" hereinafter).

Ettinger discloses an imaging device (5; Fig. 1).

Ettinger fails to disclose the step of characterizing a mounting condition for a proximal bone fragment attachment apparatus and a distal bone fragment attachment apparatus further comprises the steps of: a) generating a digital x-ray image comprising a plurality of individual images, wherein the plurality of individual images correspond to a plurality of identifiable shapes associated with the imaging device and with the portion of body tissue; b) detecting an edge of each of the plurality of individual images; c) identifying outlines from the plurality of individual image edges that correspond to the plurality of identifiable shapes associated with the imaging device; d) determining the geometric parameters associated with each of the identified outlines; e) characterizing a coordinate system associated with the imaging device based on the determined geometric parameters; f) determining one or more anatomical axes associated with the portion of body tissue; and g) characterizing the physical configuration of the portion of body tissue based on the one or more anatomical axes and the coordinate system. h) repeating steps a) through h) for a second digital x-ray image.

Meulenbrugge discloses forming X-ray images at different angles of a patient during a step of rotating an X-ray device about a longitudinal axis of a support {col. 3, lines 9-23} and converting the X-ray images to digital information at a rate of 25 images per second {col. 6, lines 35-55}.

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Ettinger in view of Meulenbrugge in order that the step of characterizing a mounting condition for a proximal bone fragment attachment apparatus and a distal bone fragment attachment apparatus further comprises the steps of: a) generating a digital x-ray image comprising a plurality of individual images, wherein the plurality of individual images correspond to a plurality of identifiable shapes associated with an imaging device and with the portion of body tissue; b) detecting an edge of each of the plurality of individual images; c) identifying outlines from the plurality of individual image edges that correspond to the plurality of identifiable shapes associated with the imaging device; d) determining the geometric parameters associated with each of the identified outlines; e) characterizing a coordinate system associated with the imaging device based on the determined geometric parameters; f) determining one or more anatomical axes associated with the portion of body tissue; and g) characterizing the physical configuration of the portion of body tissue based on the one or more anatomical axes and the coordinate system. h) repeating steps a) through h) for a second digital x-ray image. Doing so would have facilitated evaluating the relative position of bone fragments intraoperatively, thereby permitting the surgeon to better determine how to adjust the device.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ettinger in view of Meulenbrugge, as above, and further in view of Trapet (US 6023850).

Ettinger fails to disclose the imaging device comprises three balls, wherein the first ball is connected to a first end of a first rod, the second ball is connected to a first end of a second rod, the third ball is connected to a first end of a third rod, and a second end of the first rod is connected to a second end of the second rod and a second end of the third rod; the first rod, the second rod, and the third rod are orthogonally opposed; and the point where the second end of the first rod is connected to the second end of the second rod and the second end of the third rod comprises a fourth ball.

Trapet discloses a cube with balls (3) at each corner and connectors (5) for cube edges {Fig. 3a}.

It would have been obvious to a person having ordinary skill in the art to have modified Ettinger in view of Meulenbrugge, as above, and further in view of Trapet to include the imaging device comprises three balls, the imaging device comprises three balls, wherein the first ball is connected to a first end of a first rod, the second ball is connected to a first end of a second rod, the third ball is connected to a first end of a third rod, and a second end of the first rod is connected to a second end of the second rod and a second end of the third rod; the first rod, the second rod, and the third rod are orthogonally opposed; and the point where the second end of the first rod is connected to the second end of the second rod and the second end of the third rod comprises a

Art Unit: 3775

fourth ball. Doing so would have increased the three-dimensional character of the device to improve the visibility of the device in imaging systems.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN SEVILLA whose telephone number is (571)270-5621. The examiner can normally be reached on Monday through Thursday, 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THOMAS C. BARRETT can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3775

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTIAN SEVILLA/

Examiner, Art Unit 3775

/EDUARDO C. ROBERT/

Supervisory Patent Examiner, Art Unit 3733